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09/673,292	10/13/2000	Denise L. Faustman	MGH-002.1 PUS	5350

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,292	FAUSTMAN, DENISE L.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/26/00*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction requirement received on 3/19/04 has been entered. Claims 1-42 are pending in the instant application. Claims 31-42 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/19/04. Claims 1-30 are currently under examination in the instant application. An action on the merits follows.

Election/Restrictions

Applicant's election with traverse of the subject matter of group I in the reply filed on 3/19/04 is acknowledged. The traversal is on the ground(s) that the restriction was applied under 35 U.S.C. 121 and not under 35 U.S.C. 121 and 371 as required for national stage filings, and further that the claims are all so linked as to form a single inventive concept under PCT Rule 13.1. In response, the applicant is notified that the subject matter of groups I and II have been combined. Therefore, in view of applicant's election of the subject matter of group I, claims 1-30 are under examination in the instant application. In regards to the restriction between the subject matter of claims 1-30 and the subject matter of claims 31-42, groups III-VIII, applicant's traversal has not been found persuasive. The office maintains that restriction between the subject matter of group I (claims 1-30 as combined), and the subject matter of groups III-VIII is proper under both 35 U.S.C. 121 and 371. As noted by applicants, " A group of inventions is considered

linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common special technical feature." (MPEP 1893.03(d)). In the instant case, the invention of group I and the inventions of groups III-VIII do not share at least one common special technical feature. The subject matter of group I involves nucleic acids encoding a TAP splice variant. Thus, the special technical feature for group I, claims 1-30, is the nucleic acid encoding a TAP splice variant. As noted in the previous office action, the nucleic acids of invention I, the polypeptides of invention III and IV, and the antibodies of invention V have substantially different structures and properties, are made using substantially different techniques, have different modes of operation, different functions, and different effects, and can be used for substantially different purposes. Thus, they do not share the same "special technical feature". Further, the method of group VI comprise using any means of gene therapy to provide normal TAP heterodimer expression which encompasses administering nucleic acids encoding wild type TAP-1 or TAP-2 or other genes which might regulate the expression of endogenous TAP genes. Thus, the special technical features of groups I and VI are not the same. Likewise, the method of group VII comprises removing lymphocytes from an individual, and determining the expression of TAP isoforms, transfecting the cells which whichever isoform is inadequately expressed, and re-introducing them into the individual. As such, the special technical feature of group VI involves ex vivo gene therapy, including detecting TAP expression. The methods of group I are in vitro methods and the detection of TAP expression does not require the use of nucleic acids encoding TAP splice variants. Finally, the method of group VIII comprises detecting the expression of TAP isoforms and correlating any changes in expression with a disease. Again, the method of detection of TAP expression does not require the use of nucleic

acids encoding TAP isoforms since the method can be followed using antibodies against the various TAP protein isoforms. Thus, group I and groups III-VIII do not share the same special technical feature and are properly restrictable one from the other.

The requirement is therefore still deemed proper and is made FINAL.

Nucleic acid and/or Amino acid Sequences

This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below and on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages 7 and 27-28 of the specification contain amino acid sequences not identified by SEQ ID NOS. Please note that compliance to 37 CFR 1.821-1.825 requires that the specification be amended to recite SEQ ID NOS. for **each** recitation of a sequence in the specification. If the sequences not identified by SEQ ID NOS are present in the paper and CRF listings, applicant may fully comply with 37 CFR 1.821 by amending the specification to include the proper SEQ ID NOS. If the sequences are not present on the filed paper and CRF listings, then new paper and CRF sequence listings are required as set forth in the attached Notice to Comply.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 4, 8, 10, 14, 16, 20, 22, 26, and 28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible or a well established utility. The claims recite nucleic acids encoding an amino acid sequence of SEQ ID NO:25 or which have the polynucleotide sequence of SEQ ID NO. 24.

The specification discloses the isolation of a cDNA sequence having the polynucleotide sequence of SEQ ID NO:24 from a cDNA library using a human TAP1 exon 8 probe. SEQ ID NO:25 is the predicted amino acid sequence based on the nucleic acid sequence of SEQ ID NO:24. The specification states that the nucleic acid of SEQ ID NO:24 can be used to express the predicted protein of SEQ ID NO:25 and that the protein can be used to alter peptide transport in cells or treat diseases such as autoimmune disease. However, while the disclosed cDNA sequences shares homology to human TAP1 and includes exons 1-8 of human TAP1, the cDNA lacks exons 9-11 and the human TAP1 3' untranslated region and instead includes at least fifteen additional nucleic acids residues which may encode 5 additional amino acids, and a putative 3'untranslated region. The specification does not provide any evidence that the cDNA is in fact translated in cells *in vitro* or *in vivo*, or any translated protein in fact encodes the predicted sequence of SEQ ID NO.25. Further, the specification does not provide any guidance concerning any actual properties of the predicted protein, or provide any evidence that a protein encoded by SEQ ID NO:24 or corresponding to SEQ ID NO:25 has functional properties similar to TAP1 or is capable of forming a heterodimer with another TAP isomer and transporting peptides across the ER. It is further noted that the specification does not demonstrate or establish a link between the expression or lack thereof of SEQ ID NO:25 with any disease or condition. Thus, the nucleic

acids, expression vectors, and cells comprising SEQ ID NO:24 or a nucleic acid encoding SEQ ID NO:25 have no specific or substantial utility, rather, the specific and substantial utility of the transgenic cells and mammals of the instant invention requires further research to identify or reasonably confirm. (see *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689 (US SupCt 1966). It is further noted that since splice variants of TAP1 or TAP2 were not known in the prior art, a well-established utility for the claimed nucleic acids does not exist.

Applicant is referred to the Revised Utility Examination Guidelines published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71441-71442 for the required specific and substantial utility. "A claimed invention must have a specific and substantial utility. This requirement excludes 'throw-away' 'unsubstantial' or 'non-specific' utilities, " (column 3, 3rd paragraph of page 71441). In the current Office practice, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Claims 2, 4, 8, 10, 14, 16, 20, 22, 26, are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, a credible or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 5-6, 11-12, 17-18, and 23-24 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-12 of prior U.S. Patent No. 6,284,879 (9/4/01), hereafter referred to as the '879 patent. This is a double patenting rejection. The claims are identical.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-9, 13-15, and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,284,879 (9/4/01), hereafter referred to as the '879 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The claims in the '879 patent recite nucleic acids encoding a TAP2 splice variant having SEQ ID NO:2, expression vectors comprising the nucleic acid, host cells transfected with the expression

vector, and methods of producing a polypeptide comprising culturing the host cell. The instant claims are similar to the '879 claims, but are broader in scope. The instant claims recite nucleic acids encoding any TAP1 or TAP2 variant or nucleic acids whose sequence is at least 95% identical to SEQ ID NO:2. As such, the claims in the '879 patent represent a species of the instant claims. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann* , 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Thus, claims 1-3 of the '879 patent render claims 1-3, 7-9, 13-15, and 19-21 of the instant application obvious.

Priority

The subject matter of claims 2, 4, 8, 10, 14, 16, 20, 22, 26, and 28 is not accorded benefit of priority to parent application 09/061,764, because SEQ ID NO:24 is not disclosed in the 09/061,764 application. Thus, the effective filing date for claims 2, 4, 8, 10, 14, 16, 20, 22, and 28 is the filing date of PCT/US99/08205, 4/15/99. The effective filing date for the subject matter of claims 1, 3, 5-7, 9, 11-13, 15, 17-19, 21, 23-27, and 29-30 is the filing date of the 09/061,764 application, 4/16/98.

Claim Rejections - 35 USC § 112

Claims 1-4, 7-10, 13-16, 19-22, and 25-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a TAP2 splice variant having the nucleic acid sequence of SEQ ID NO:4 and the amino acid

sequence of SEQ ID NO:2, expression vectors comprising said nucleic acid, isolated host cells comprising said expression vector, and methods for producing a polypeptide comprising culturing said host cell *in vitro*, does not reasonably provide enablement for isolated nucleic acids encoding any TAP1 or TAP2 splice variant or for vector, cells comprising said nucleic acids or methods of using said nucleic acids, vectors, or cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification discloses splice variants of the peptide transporter genes TAP1 and TAP2 designated TAP1iso, TAP1iso2, TAP1iso3, TAP2iso, and TAP2iso2. The specification further discloses that TAP splice variants function by forming heterodimers with either wild type TAP proteins or other splice variants, thereby forming peptide transporter complexes with altered capacity for transporting certain peptides from the cytoplasm to the endoplasmic reticulum. The specification further states that the loss of expression of one or more TAP1 or 2 splice variants may be associated with certain autoimmune disorders and teaches that nucleic acids encoding TAP1 or 2 splice variants may be used to restore or enhance peptide transporter complex expression and function.

The specification does not provide an enabling disclosure for making and using any and all splice variants of TAP1 and TAP2 from any and all species. The specification describes splice variants for human TAP1 and human TAP2 genes. The specification provides no guidance or teachings that splice variants of TAP1 and TAP2 exist for any species other than humans. The specification focuses primarily on the human TAP2 splice variant TAP2iso, which lacks exon 11 found in wild type human TAP2, but contains a novel exon 12. The specification provides

several examples demonstrating that cDNA encoding human TAP2iso, exons 1-10 and 12, produces a TAP2iso protein that is capable of forming a heterodimer with wild type human TAP1, and is further capable of transporting peptides across the ER membrane resulting in the surface expression of peptide loaded MHC class I molecules on the cell surface of T2 cells transfected with both TAP1 and TAP2iso. The specification's disclosure in regards to the existence of further splice variants of human TAP2 is limited to the detection by PCR of an additional band in some but not all normal human PBLs using a forward primer derived from TAP2 exon 9 and a reverse primer from TAP2 intron 10. In regards to the additional band identified for TAP2, the specification speculates but provides no concrete evidence that the extra length of the band is the result of a novel splicing event in which a portion of intron 10 is left attached to exons 1-10. Further, the specification does not provide guidance as to the portion or sequence of intron 10 which forms the 3' end of the mRNA. For human TAP1, the specification's examples provide partial sequencing data of additional bands amplified by the TAP1 exon 9 and TAP1 intron 10 primers. The specification also provides a complete sequence for a TAP1iso3 sequence cDNA identified using a TAP1 exon 8 primer. In regards to the additional TAP1 bands designated TAP1iso1 and TAP1iso2, again, the specification does not provide adequate guidance as to the length and sequence of the portion of intron 10 spliced to the 3' end of exon 10. Because the applicants use a single primer from intron 10 it cannot be determined that the splice variants identified by PCR do not contain additional sequences at the 3' end of the original mRNA transcripts. More importantly, the specification does not provide any evidence that the additional intronic sequences are translated, and/or that the resulting TAP1 proteins are functional both in forming heterodimers with other wild type or splice variant TAP

proteins and in transporting peptides across the ER. Likewise, the specification does not provide any evidence that the TAP2iso3 sequence isolated from the cDNA library is capable of expressing a protein or is actually translated into protein in cells *in vitro* or *in vivo,* or that any resulting protein would in fact have TAP1 functionality, i.e. the capacity to form heterodimers with TAP2 and transport peptides across the ER. Further, the specification does not demonstrate that any variant other than TAP2iso protein is capable of altering the specificity of peptide transport in a cell. Thus, due to the lack of guidance provided by the specification concerning the characteristics of splice variants of TAP1 and TAP2 other than human TAP2iso in terms of the physical characteristics of the nucleic acids themselves and their ability to generate functional TAP proteins as discussed above, it would have required undue experimentation for the skilled artisan to make or isolate the splice variants of the instant invention from any and all species. Further, based on the lack of teachings in the specification or the prior art as to the existence of TAP splice variants in species other than humans, the skilled artisan would not have considered it predictable to make or isolate TAP splice variants from other species or to produce any and all TAP splice variant proteins capable of forming heterodimers with other normal or variant TAP proteins.

The specification does not provide an enabling disclosure for altering peptide transport in any and all cells *in vitro* comprising transfecting any cell with an expression vector encoding any and all human TAP1 or TAP2 splice variants and culturing the cell under conditions suitable to produce the TAP1 or TAP2 splice variant protein. As discussed in detail above, it is unclear from the specification whether any of the human TAP1 splice variants or the TAP2iso2 variant detected by RT-PCR are actually translated into functional TAP proteins. Further, while the

specification teaches that multiple variants of the TAP1 and TAP2 mRNA are transcribed in many lymphoid cells, the specification does not disclose that any combination of TAP1 protein and TAP2 protein translated from these various mRNA species is capable of forming a functional heterodimer. In addition, besides the combination of TAP2iso and wild type TAP1, the specification does not disclose the composition or characteristics of heterodimers that result in altered peptide transport compared to the wild type transport proteins. In regards to the TAP2iso, the specification provides a working example demonstrating that the transfection of *both* wild type TAP1 and TAP2iso into the mutant cell line T2 results in restoration of MHC class I surface expression. The specification clearly states that the transfection of TAP2iso alone had no effect on class I expression (specification, page 25, lines 21-22). Thus, peptide transport requires the presence of both a TAP1 subunit and a TAP2 subunit in the cell. The working example also demonstrates that the transporter heterodimer formed with TAP1 and TAP2iso differs from the wild type transporter in its preference for transporting certain peptides. However, T2 cells lack TAP1 and TAP2 expression. The specification does not disclose or demonstrate the ability of recombinant TAP2iso to affect peptide transport in the presence of wild type TAP2 and any endogenous amount of TAP2iso. The specification is silent as to the affinity of TAP2iso for wild type TAP1 compared to that of wild type TAP2, for the ratio of wild type to variant transporter heterodimers formed in cells expressing both TAP2 and TAP2iso, and the overall effect on peptide transport in cells in which there are varying ratios of wild type TAP2 and TAP2iso containing transporter heterodimers. In the absence of any guidance from the specification concerning these parameters, the skilled artisan would not be able to predict the effect of expressing human TAP2iso in a cell on peptide transport. Therefore, in view of the state

of the art at the time of filing which does not teach that peptide transport can be altered in a cell by expressing a splice variant of a TAP protein, the lack of guidance provided by the specification for the parameters discussed above, and the breadth of the claims, it would have required undue experimentation to practice the instant invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bahram et al. (1991) Proc. Natl. Acad. Sci. USA, V. 88, 10094-10098. The applicant claims an isolated nucleic acid encoding a TAP1 or TAP2 splice variant and an isolated nucleic acid comprising a polynucleotide sequence that is at least 95% identical to a polynucleotide having the polypeptide sequence of SEQ ID NO. 2. It is noted that TAP1 and TAP2 have been identified in the literature by a variety of names including RING1 and RING2 and PSF1 and PSF2. It is further noted that the applicant's claims read on the "wild type" sequence as this sequence is one of two or more splice variants of a single gene.

Bahram et al. teaches an isolated nucleic acid, designated PSF 2, which, as the wild type sequence of TAP2, is naturally a splice variant (Bahram et al., supra, page 10095, Figure 2). Further the reported sequence of PSF2 is greater than 97% identical to the polynucleotide

sequence that encodes for SEQ ID NO. 2. Thus, by teaching all the elements of the claims, Bahram et al. clearly anticipates the instant invention as claimed.

Claims 1-2, 7-8, 13-14, 19-20, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (1995) Human Gene Therapy., Vol. 6, 1005-10017. The applicant claims an isolated nucleic acid encoding a TAP1 or TAP2 splice variant and an isolated nucleic acid comprising a polynucleotide sequence that is at least 95% identical to a polynucleotide having the polypeptide sequence of SEQ ID NO. 2. The applicant further claims expression vectors encoding said nucleic acids, host cells transfected with said vectors, and methods of producing TAP proteins and altering transport of peptides comprising transfecting cells with said vector.

Wang et al. teaches an expression vector encoding the human TAP2 gene, and the transfection of human B cells from patients with IDDM wherein the expression of the TAP2 protein results in increased transport of peptides across the endoplasmic reticulum as measured by increased surface expression of peptide loaded MHC class I molecules on the cell surface compared to untransfected B cells from the same source (Wang et al., supra, page 1007, figure 1, and pages 1008-1010). Thus, by teaching all the elements of the claims, Wang et al. anticipates the instant invention as claimed.

Claims 3-6, 9-12, 15-18, 21-24, and 27-30 are free of the prior art of record.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

Application No.: 09/673,292

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: Amino acid sequences on pages 7, and 27-28 are not identified by SEQ ID NOS.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

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